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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,877	08/01/2003	Robert Joseph Panek JR.	S-8465 (1)	3038

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TYCO HEALTHCARE GROUP LP
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EXAMINER

KOEHLER, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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3726

MAIL DATE	DELIVERY MODE
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06/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,877	Applicant(s) PANЕК ET AL.	
	Examiner Christopher M. Koehler	Art Unit 3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagstetter et al. (US Patent No. 5,092,462).

Claim 13:

Sagstetter teaches a modular construction (figure 13) of its apparatus for unwinding double ended needles. The sole purpose of a modular construction, such as that taught by Sagstetter, is the ease of replacement of modules having different configurations, otherwise the modular embodiment of Sagstetter would merely constitute surplusage as the first embodiment having fixed adapters (30, 90, figure 1) would not need to be modified to include modular adapters. Therefore, it is inherent from the disclosure of Sagstetter that modules having different configurations for the removal of needles from different needle carriers are to be used in the modular embodiment (figure 13). Thus while it is not explicitly disclosed in Sagstetter, the modular construction carries with it the inherent implication that one configuration of a module is to be replaced with other configurations of modules based on the configuration of the needle holders used. Further, Sagstetter discloses two unwinding configurations (30, 90, figure 1) for unwinding needles from two different needle holders

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(34, 54, figures 1 and 3) with one of the two configurations shown in the modular embodiment (the unwinding configuration of 230 is the same as 30). Therefore, Sagstetter teaches a method of unwinding a second needle portion (48) from a second needle holder (34) of a needle system having a second configuration (figure 3; 34 different from 54) using a container system (figure 1) including a receptacle (10) and a lid (12, 250), the lid having an aperture (90, figure 3) configured to unwind a first needle portion (62) from a first needle holder (54) of a needle system having a first configuration (figure 3; 54 different from 34), said method comprising the steps of: (a) engaging an adapter (230) having an adapter aperture (same configuration as 30) configured to receive the needle system having the second configuration (34, 48) in the lid aperture, thereby modifying the lid from being configured to unwind the first needle portion from the first needle holder of the needle system having the first configuration to being configured to unwind the second needle portion from the second needle holder of the needle system having the second configuration (see figure 13 and discussion above); (b) inserting at least a portion of the needle system having the second configuration into the adapter aperture (use is best shown in figure 3), thereby engaging the second needle portion to resist rotation of the second needle portion with respect to the adapter (col. 4, lines 45-60); and (c) rotating the second needle holder with respect to the adapter, thereby unwinding the second needle portion from the needle system having the second configuration such that the second needle portion can be released into the receptacle (col. 4, lines 45-60).

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Claims 16 and 17:

Sagstetter teaches that the engaging step comprises engaging two or more flanges (232 on four sides) provided on the adapter with an edge of the lid (bordering the aperture).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagstetter in view of Shaw (US Patent No. 6,474,472).

Claims 14 and 15:

Sagstetter teaches the structure of claim 13 above and additionally teaches a detent and depression formed on cooperating parts of the adapter but does not explicitly teach two or more detents formed on the adapter with depressions formed on the lid.

Shaw teaches a lid for needle disposal systems (102, figure 19) having an adapter (104) fitted therein and removably secured thereto by at least two detents (110) formed on the adapter and the lid.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided detents on the edges (232) of the adapter of Sagstetter and cooperating depressions on the inside edges of the aperture of

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Sagstetter, in light of the teachings of Shaw, in order to provide additional securement of the adapter to the aperture and assist in the alignment of the adapter to the lid.

Response to Arguments

5. Applicant's arguments filed 2/18/2009 have been fully considered but they are not persuasive.

6. Applicant's amendment to claim 13 necessitated the clarification of the rejection of claim 13 which addresses applicants' arguments as to the modification between the first and second needle system configurations.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Koehler whose telephone number is (571)272-3560. The examiner can normally be reached on Mon.-Fri. 7:30A-4:00P.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David P. Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jermie E Cozart/
Primary Examiner, Art Unit 3726

/C. M. K./
Examiner, Art Unit 3726